REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following comments.

Applicants acknowledge the receipt of the Notice of Non-compliance mailed March 22, 2005. In response, new claim 41 has been amended to remove any markups. Also applicants have changed the status identifiers for claims 10 and 34 from "Original" to "Currently amended."

Presently, claims 1-4, 6, 10, 15, 16, 20, 21, 34, and 35 are amended. Additionally, claims 41 and 42 have been added. Applicants request that the examiner enter the above claim amendments and new claims as no new matter has been added. In particular, exemplary support for new claim 41 may be found in the original claim 1 as well as the specification on page 7, lines 28-30. Support for new claim 42 may also be found in original claim 1 and page 4, lines 25-29. Finally, support for the amendments to claim 1 may be found in the specification on page 1, line 34 - page 2, line 8, and page 4, lines 16-20. Upon entry of this response, claims 1-42 will be pending.

I. Rejection under 35 USC §112

A. Rejection for alleged lack of written-description support

Claims 1-29, 31-40 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written-description requirement. The examiner argues that "the instant specification teaches the construction of two plasmid replicons" but does not teach the structural/functional characteristics of all of the potential variations of these vectors. Applicants respectfully disagree.

Applicants have amended claim 1 to cover a vector comprising:

a. lactic acid bacterial DNA;

b. a gene coding for an amber suppressor which is a tRNA comprising the CUA anticodon; and

c. a replicon making the vector capable of replicating in a lactic acid bacterium;

but lacking an antibiotic resistance gene.

The specification describes in detail each of these structural characteristics. For example, the specification describes the claimed vector as lacking an antibiotic resistance gene on page 1, line 34 - page 2, line 8, and page 4, lines 16-20. The specification also describes sources of the DNA material for the invention, page 6, lines 15-19. Additionally, the specification also discloses the various mutations of the amber suppressor suitable for the invention, page 6, line 28-33 and provides various examples of suitable suppressors on page 8, line 12-34 of the specification. Finally, the specification provides examples of replicons capable of replicating in a lactic acid bacterium on page 9, lines 25-30, along with the size of the claimed vectors (page 10, lines 12-15). Furthermore, one of skill in the art would know how to select a replicon capable of replicating in a desired bacterial strain. See Bolivar et al. 1977, Exhibit A, and Pedersen *et al.* 1994, submitted as IDS, A17, Exhibit B.

Accordingly, applicants' specification provides a clear indication that applicants, at the time their application was filed, possessed the claimed invention.

B. Rejection for alleged non-enablement

Claims 1-40 also stand rejected under Section §112 for allegedly failing to satisfy the enablement requirement. The examiner found that the claims cover a broad genus of recombinant vectors and, hence, that the skilled person would not be able to determine the additional vectors that would meet the requirements of claim 1. Applicants respectfully disagree.

As explained above, applicants have amended claim 1 to clearly describe the structure of the claimed genus. Thus, one of skill in the art would easily be able to obtain the claimed vectors using only routine experimentation. Additionally, a person skilled in the art would know how to test a particular vector and would easily recognize whether this vector falls within the functional characteristics of the claimed vectors, i.e. being stably maintained in an industrial useful strain, substantially not causing growth inhibition and reducing acidification in a broad range of host strains. Specification page 4, lines 16-20 and page 4, line 31 – page 5, line 13.

Furthermore, as requested by the examiner, applicants have amended claim 15 to remove the "mutants, variants and derivatives" language from the claims. Given the specification's description and the clearly defined scope of the present claims, both set forth above, one of skill in the art would be able to practice the claimed invention.

Finally, per the examiner's request, applicants have attached a declaration by Jan Skouv that states that the biological materials necessary to practice the invention are deposited under the Budapest Treaty and are available for use. See attached Exhibit C.

Therefore, one of skill in the art is able to practice the present invention without undue experimentation, hence, the present invention is enabled and that this rejection should be withdrawn.

C. Rejection for alleged indefiniteness

Claims 1-40 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter that the applicants regard as their invention. Accordingly, applicants have amended the claims per the examiner's requests.

Specifically, applicants amended claim 1 to clarify the structural characteristics of the claimed vector i.e., a vector "comprising (a) lactic acid bacterial DNA, (b) a gene coding for an amber suppressor that is a tRNA comprising the CUA anticodon, and (c) a replicon making the vector capable of replicating in a lactic acid bacterium." Also, claim 41(ii), formerly claim 1(ii), has been amended to specify that the DSM 12109 strain is used to compare the functional properties of the claimed vector against the functional properties of the parent strain and to clarify the acidification rate variation allowed between the parent strain and the strain containing the claimed vector. Additionally, claims 4, 6, 10, and 20 were amended to recite "obtained from" rather than "derived from," claim 6 also was amended to cover "a heterologous promoter" rather than "a promoter not naturally related to the gene," claim 15 was amended to remove "mutants, derivatives, or variants," claim 16 was amended to recite "further comprises," claim 21 was amended to specify that the gene product is "a part of the nisin synthesis pathway or leading to nisin resistance" and claim 34 was amended to recite "per gram composition." Finally, claim 35 was amended to comport with proper claim structure and language and to clarify that claim 35 covers the "use of a the composition ... as a starter culture in the preparation of a product."

Separately, the examiner found that there was not a clear antecedent basis for the phrase "the gene product" as used in claims 16 and 18. Applicants respectfully disagree. Amended claim 16 now provides proper antecedent basis for the phrase "the gene product" as used in dependant claim 18.

The examiner also found that claims 32 and 33 were vague and indefinite because they recite the phrase "pure culture." Applicants argue that "the phrase "pure culture" is clearly defined on

page 12, lines 5-6 of the specification, as a culture containing biomass of one single isolate of a lactic acid bacterial species, *i.e.*, a clone originating in principle from one cell.

Applicants believe that the present claims clearly define the subject matter of the present invention. Therefore, applicants argue that the above rejections should be withdrawn and the present claims allowed.

II. Rejection Under 35 USC §101

Claim 35 is rejected under 35 U.S.C. §101 because it is not a proper process claim. As explained above, applicants have amended claim 35 and believe that it is now written in proper claim format. Therefore, applicants believe that the present rejection should be withdrawn and the claim allowed.

III. Rejection Under 35 USC §102

Claims 1-4, 7, 9-16, 22-24, 28-29, 31-33, and 36 are rejected for anticipation by Dickely *et al.* Applicants respectfully disagree.

At the outset, applicants would emphasize that the specification defines a "food-grade vector" as a recombinant vector that "consist[s] essentially of lactic acid bacterial DNA" (page 2, lines 11 & 12) and that lacks an antibiotic resistance gene (see page 4, lines 2 & 3). By the same token, amended claim 1 recites a vector that lacks an antibiotic-resistance gene but that does comprise (a) DNA from lactic acid bacterial origin, (b) a gene coding for an amber suppressor that is a tRNA comprising the CUA anticodon, and (c) a replicon that renders the vector capable of replicating in a lactic acid bacterium. In contrast, both of the cloning vectors disclosed by Dickely *et al.* (1995), pAK89 and pAK89.1, contain a gene coding for erythromycin resistance.

Furthermore, the Dickely reference does not anticipate a recombinant vector "consisting essentially of lactic acid bacterial DNA" (claim 42). The Dickely vectors, pAK89 and pAK89.1, contain not only a gene coding for erythromycin resistance but also DNA from *E. coli*, along with DNA from a lactic acid bacterium (see Dickely's Table 3). As evidenced by the specification, *e.g.*, at page 1, lines 23-32 and page 2, lines 10-12, the presence of the *E. coli* DNA disqualifies the Dickely vectors for food use; that is, they are not "food grade." It is apparent, therefore, that a vector

"consisting essentially of" the constituents recited in claim 42 would not include DNA, such as *E. coli* DNA, that affects so material a characteristic as its "food grade" quality.

For these reasons alone, claim 1 and claim 42 are separately patentable over the prior art illustrated by Dickely *et al.* More generally, applicants would emphasize that the presently claimed invention distinguishes over the art because the recited cloning system is stably maintained and useful in any industrial lactic acid bacterial strain, in contrast to conventional cloning systems. In addition, the claimed cloning system does not cause growth inhibition and reduces acidification in a broad range of host strains, especially in industrial useful lactic acid bacteria. These characteristics make applicants' claimed vectors useful in the manufacturing of food and feed products.

In fact, at the time of filing the art taught away from the use of an amber suppressor, since it was conventional wisdom that the amber suppressor would cause growth inhibition since this was the result seen with an ochre suppressor. Furthermore, at the time of filing for the present application, the whole lactic acid bacteria genome was not known; hence, one would not know how many amber stop codons (UAG) an amber suppressor would recognize in a cell, compared to an ochre suppressor.

In summary, the present claims do not read on the cloning vectors taught by the cited publication, and so the subject matter of the claims is novel over the art at the time of filing. Applicants therefore submit that this rejection should be withdrawn.

IV. Priority

Applicants submit, herewith, a new application data sheet, Exhibit D, which properly reflects the present application's priority information. Additionally, attached as Exhibit E is a copy of PCT/IB/304 indicating that the International Bureau received a copy of each of the priority applications on May 12, 1999. Therefore, applicants do not believe they are required to submit additional certified copies.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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